JUN - 7 2001

K011001

10. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

A. Submittor Information

SATELEC Medical
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FRANCE

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Contact Person: Pascal Dupeyron
Regulatory Affairs

Date Prepared: March 9, 2001

B. Device Identification

Device Classification Name:	Device, Electrical Dental Anesthesia
Proprietary Name:	TEAM UP™
K Number:	K011001

C. Identification of Predicate Device(s)

TEAM UP™ is substantially equivalent to the following previously cleared and currently marketed devices, Cedeta Dental International MK2 (K915717) and 3M System 8670 (K935304). However, the Cedeta device uses HF Current, while the 3M System uses AC current up to 60 mA, whereas the TEAM-UP from Satelec uses DC micro-current up to 15 μA.

D. Device Description

TEAM UP™ is a hand-held, stand-alone, electronically generated microprocessor-controlled direct micro-current generator designed for pain control in place of local pharmaco-chemical pain control during scaling procedures. It is connected through a universal sterilizable handpiece (model PAM) and one of 2 scaler tip inserts to the FDA cleared Suprasson P5 Booster ultrasonic generator from Satelec (K961158) by a single lead. The battery-powered device allows the patient to manually control the micro-current intensity for pain control in the 2 μA to 15 μA micro-current range.

Electric output testing was conducted and demonstrated that TEAM UP™ safely delivers a controlled 2 μA to 15 μA micro-current in the representative 0 to 2 MΩ patient resistance range on surface contacts larger than at least 0.18 mm^2 with the specified Suprasson P5 inserts. Leakage tests performed in single fault failure mode demonstrated that the device operated well within the maximum UL 2601.1 standard limit.

Clinical tests established that in a 41 patient randomized double-blind study, TEAM UP™ brings a quantitatively measured comfort in reducing pain in 68.3% of the patients. A mean decrease in pain by a factor of about 1/3 was recorded in all patients, with no significant difference between male and female patients.

E. Substantial Equivalence

The Satelec TEAM UP™ device is substantially equivalent to the Cedeta Dental International MK2 (K915717) and 3M System 8670 (K935304). Differences that exist between these devices relating to technical specifications, materials, and physical appearance do not affect the safety or effectiveness of the Satelec TEAM UP™ relative to its predicates.

The Satelec TEAM UP™ is used in pain control in place of local pharmaco-chemical pain control for various dental scaling procedures in adults and pediatrics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2001

SATELEC
C/O Mr. Jean-Luc Boulnois
President
Interactive Consulting, Incorporated
70 Walnut Street
Wellesley, Massachusetts 02481

Re: K011001
Trade Name: Team-Up™ Dental Electronic Anesthesia System
Regulatory Class: Unclassified
Product Code: LWM
Dated: March 8, 2001
Received: March 9, 2001

Dear Mr. Boulnois:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011001

Device Name: TEAM-UP™

Indications For Use:

To aid in the management of discomfort associated with non-surgical scaling and root planing.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011001